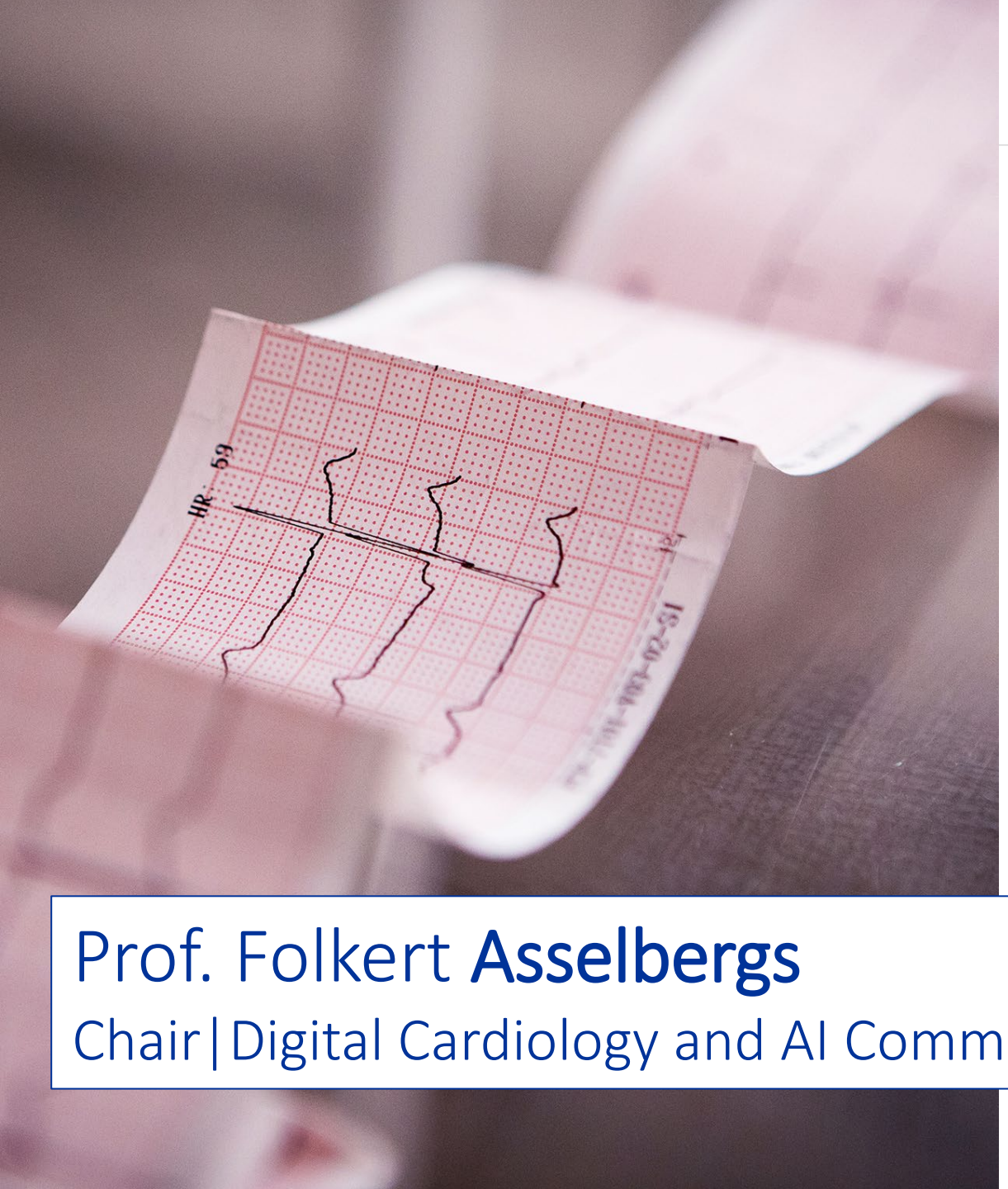


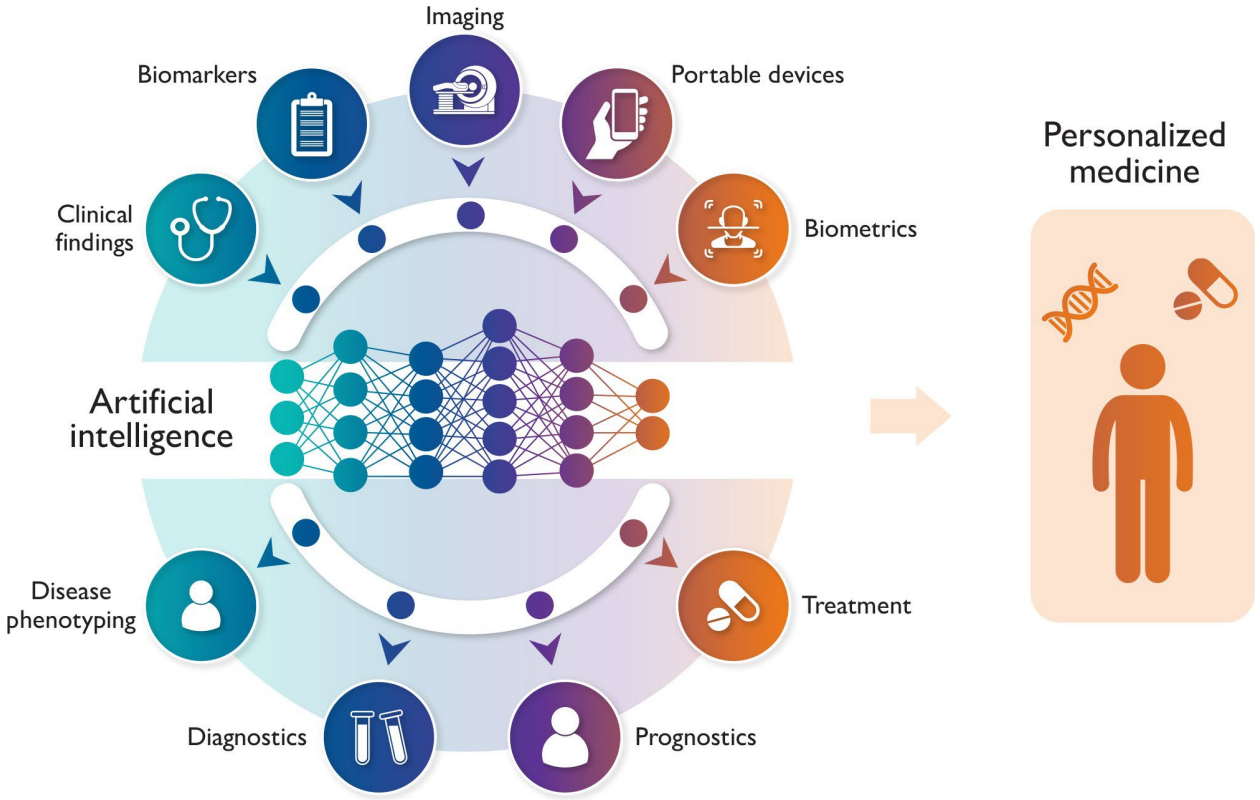
AI in cardiovascular care

From development to implementation – a roadmap for EU-wide deployment of AI in CV care

Prof. Folkert **Asselbergs**
Chair|Digital Cardiology and AI Committee of the ESC

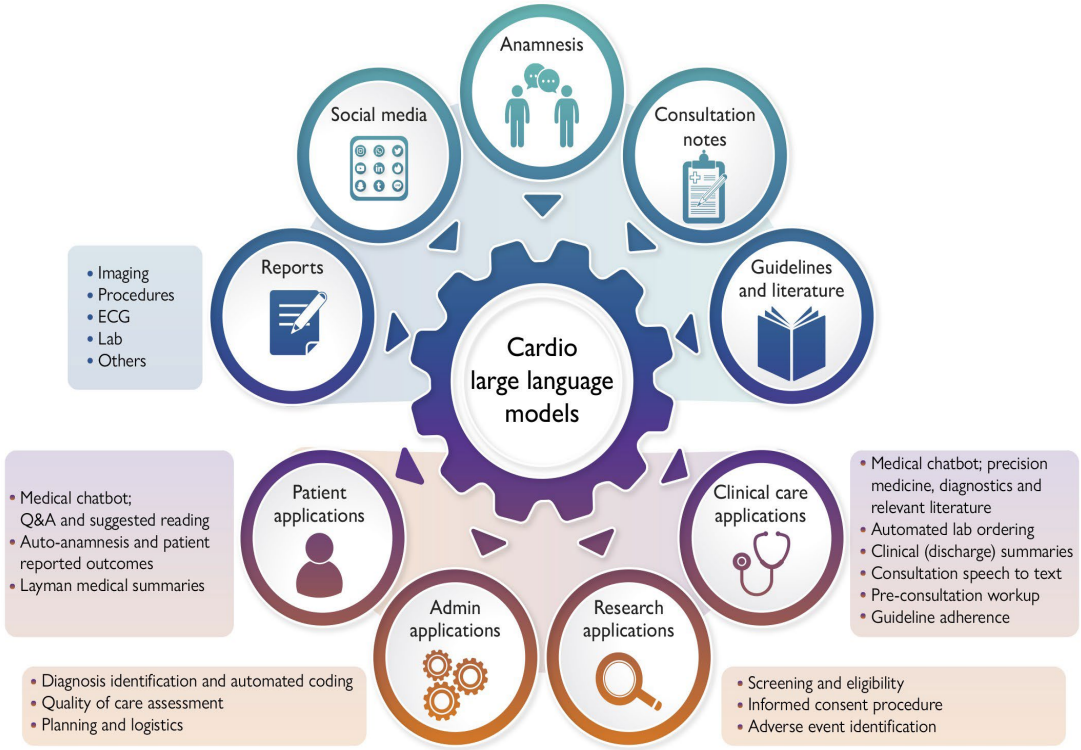
ESC
European Society of Cardiology

Artificial intelligence in cardiovascular medicine: clinical applications



Eur Heart J, 2024 4291–4304

Artificial intelligence: revolutionizing cardiology with large language models

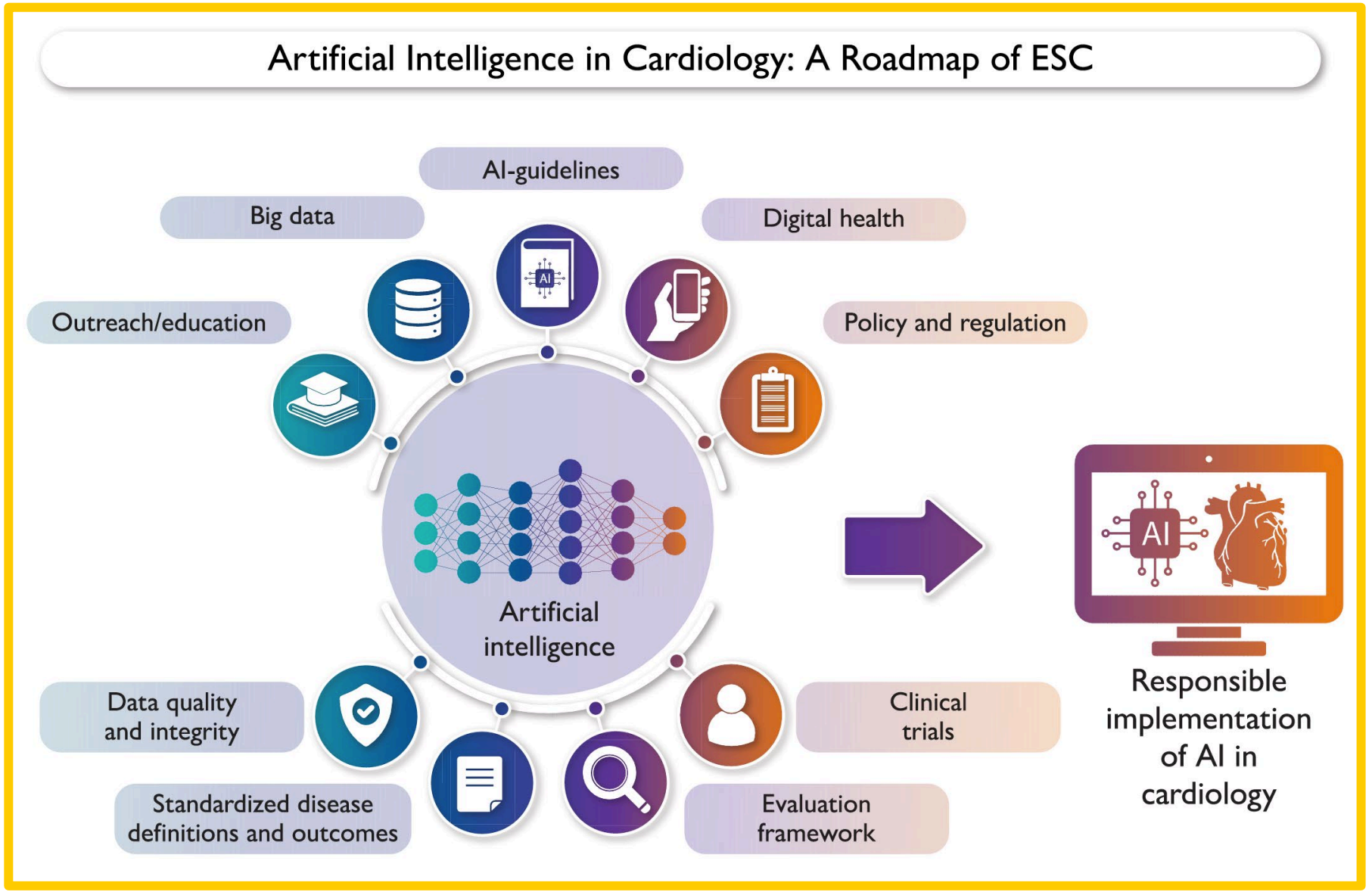


European Heart Journal. 2024: 332–345

From potential to implementation

Potential ≠ implementation

The three “valleys of death”

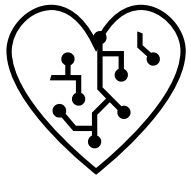


European Heart Journal; 2025, 677–679

Digital Cardiology and AI: Guidelines

Supporting assessment and usage of AI in cardiology in collaboration with the Clinical Practice Guidelines committee

Assessment of AI in ESC Guidelines

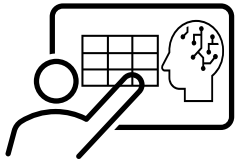


Developing evidence assessment concepts for AI-based clinical solutions

Guideline Digitalization

Digital representation and interaction with guidelines

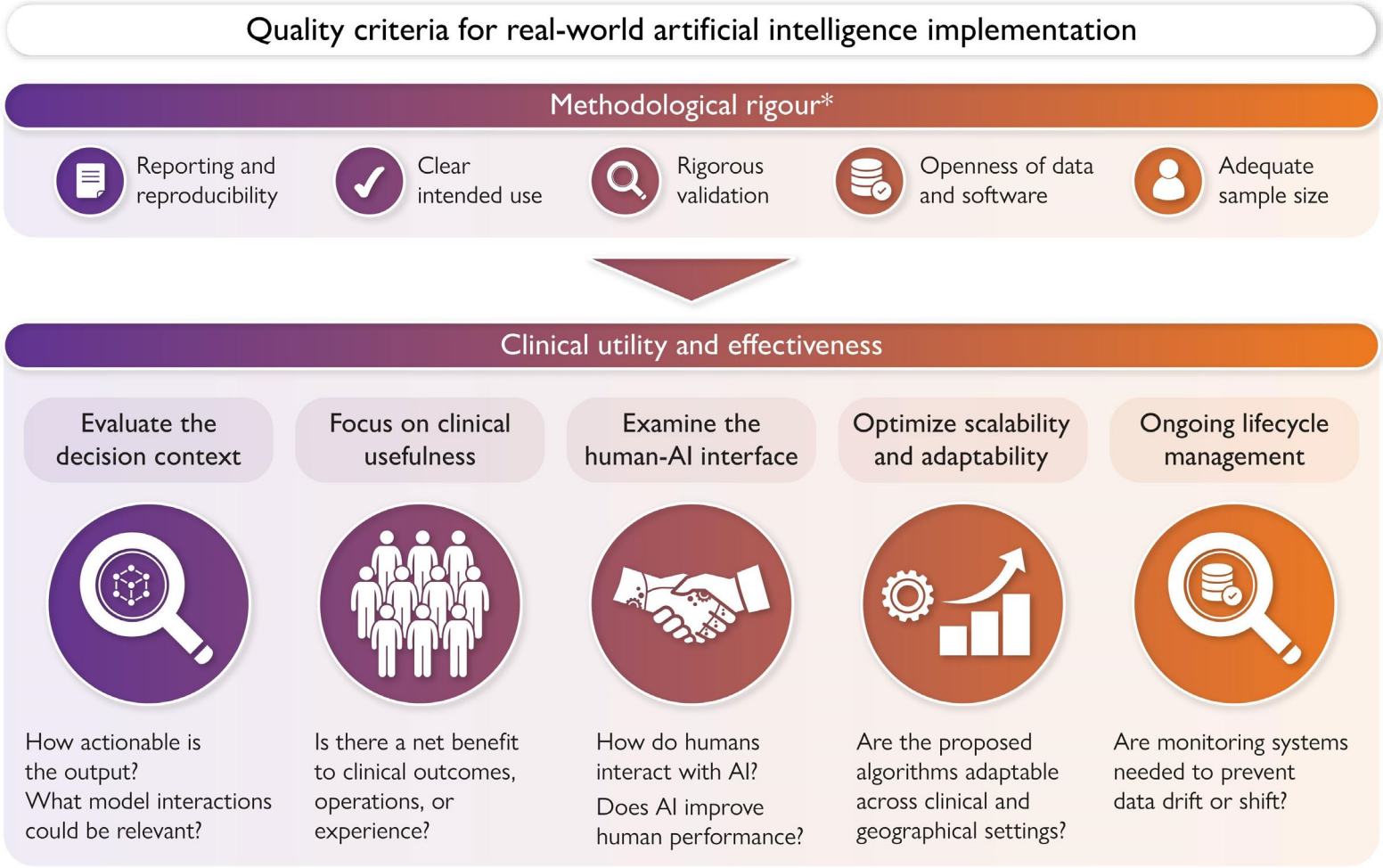
AI Support for Guideline Task Forces



Support research and generation of evidence tables with AI tools

ESC chat

Standards are needed



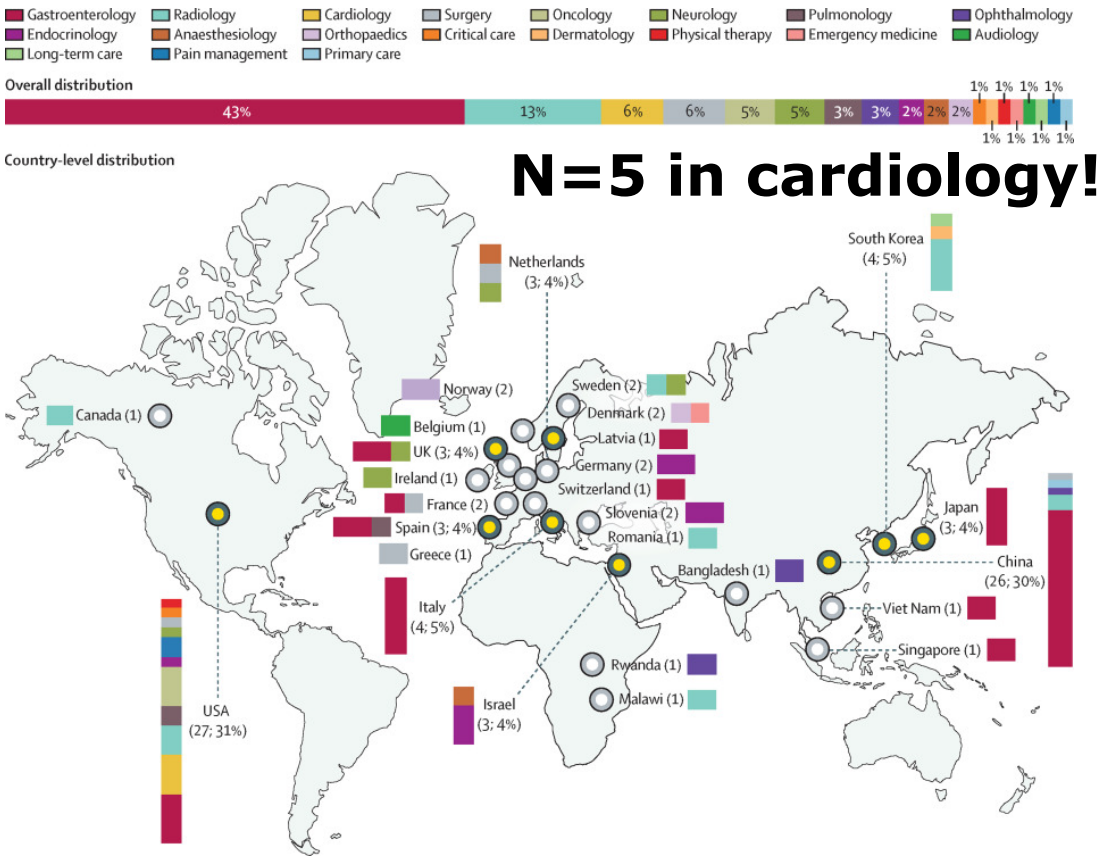
AI, artificial intelligence; *, Van Royen FS, *et al. European Heart Journal.*

Oikonomou EK, *et al. European Heart Journal.*

Eur Heart J, ehag121, https://doi.org/10.1093/eurheartj/ehag121

EMA

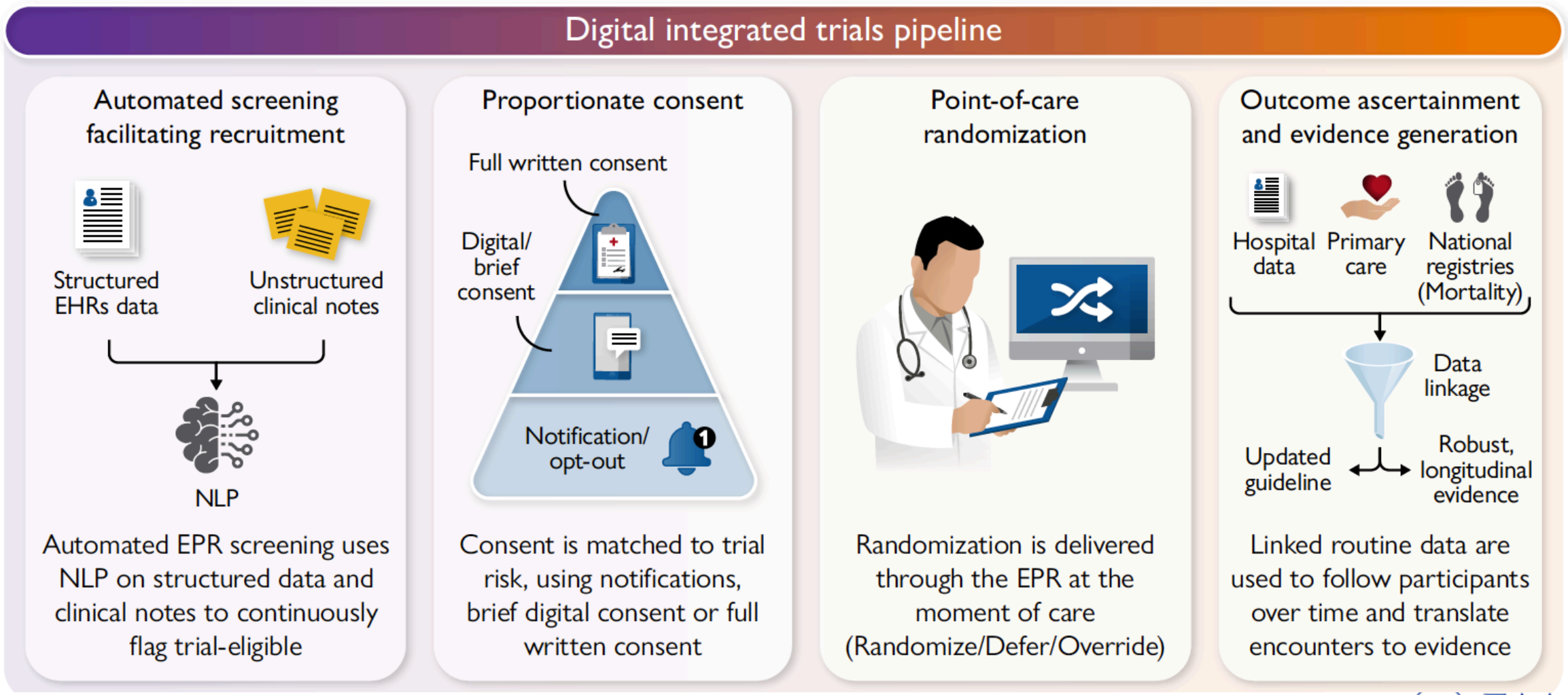
Randomized Clinical Trials urgently needed to grade level of evidence for AI algorithms



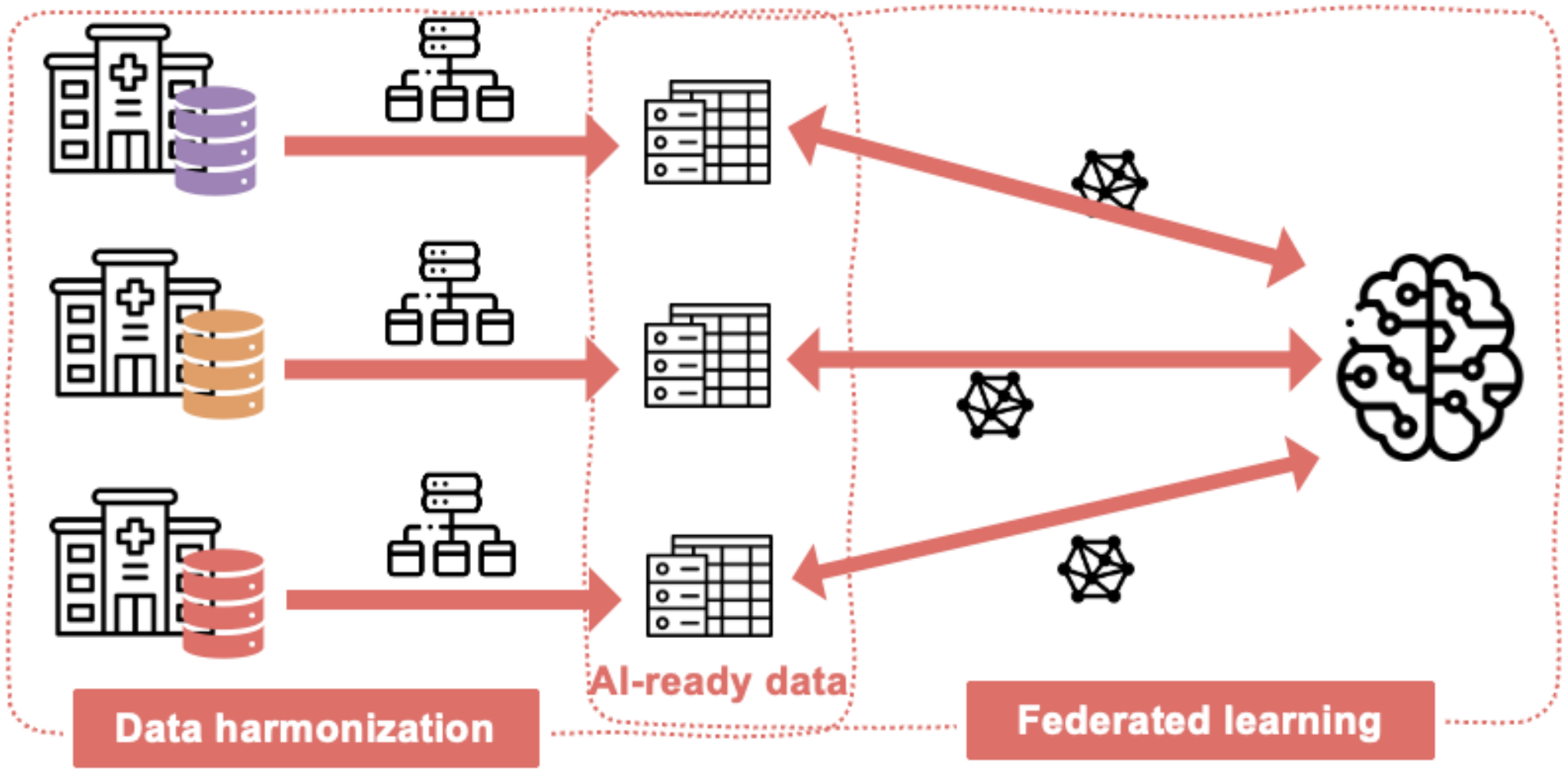
Lancet Digit Health 2024; e367–73

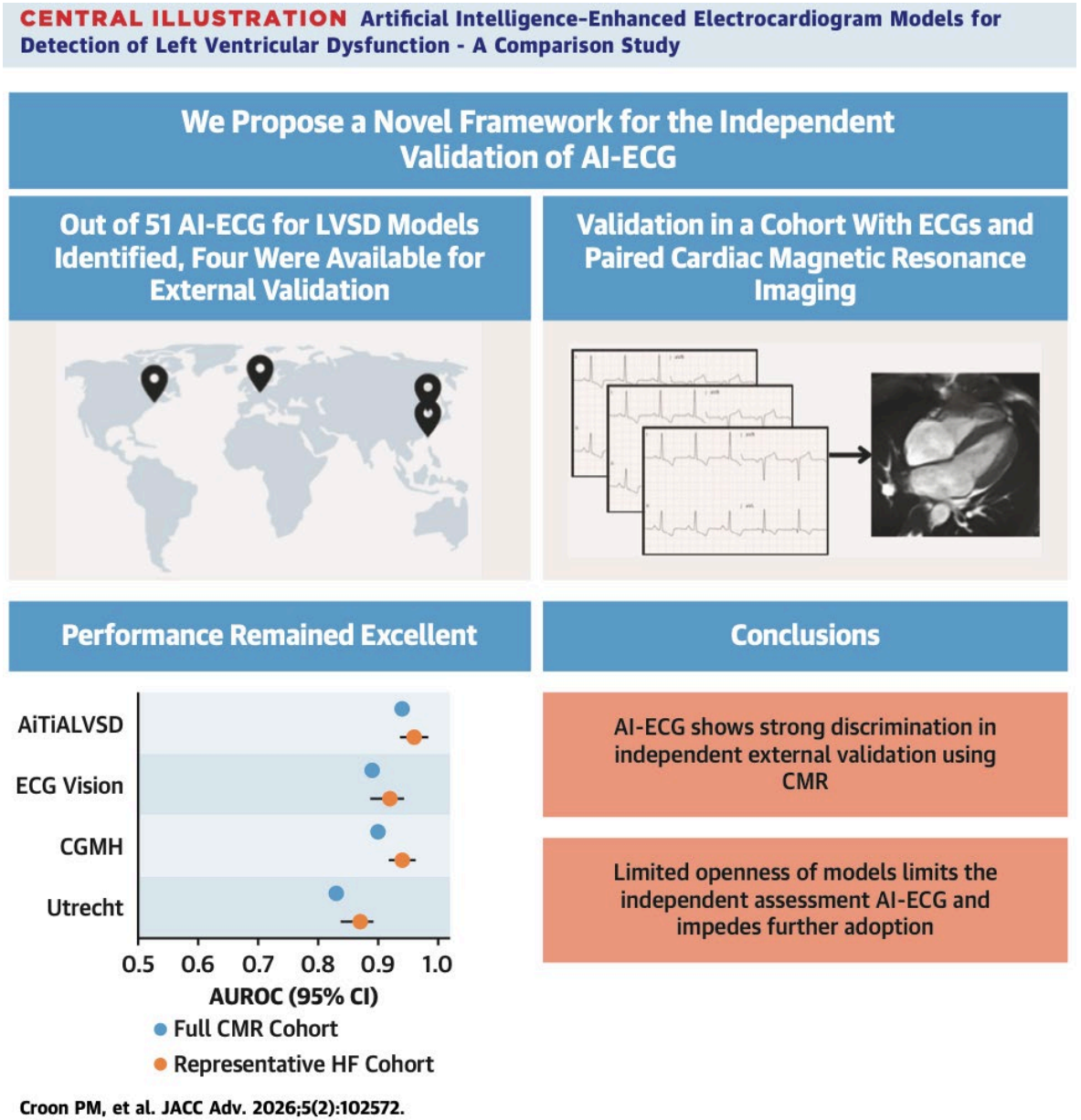
Classes of recommendations	Definition	Wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended or is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/ efficacy of the given treatment or procedure.	
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy.	Should be considered
Class IIb	Usefulness/efficacy is less well established by evidence/opinion.	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

Rapid-cycle, pragmatic RCT's needed for AI validation



Digital trial network needed





- Comparative studies needed
- Benchmarking data for external validation
- Representativeness
- Post-deployment evaluation
- AI passport

A living record of the full lifecycle of AI models

Captures structured metadata from study definition to deployment and passport generation.

Promotes transparency and traceability in healthcare AI

Tracks how data is used, models are built, and decisions are made throughout development.

Supports reproducibility and consistent model governance

Documents model configurations, parameters, and evaluation metrics for auditability.

Bridges technical documentation and stakeholder needs

Provides both detailed machine-readable metadata and user-friendly reports.

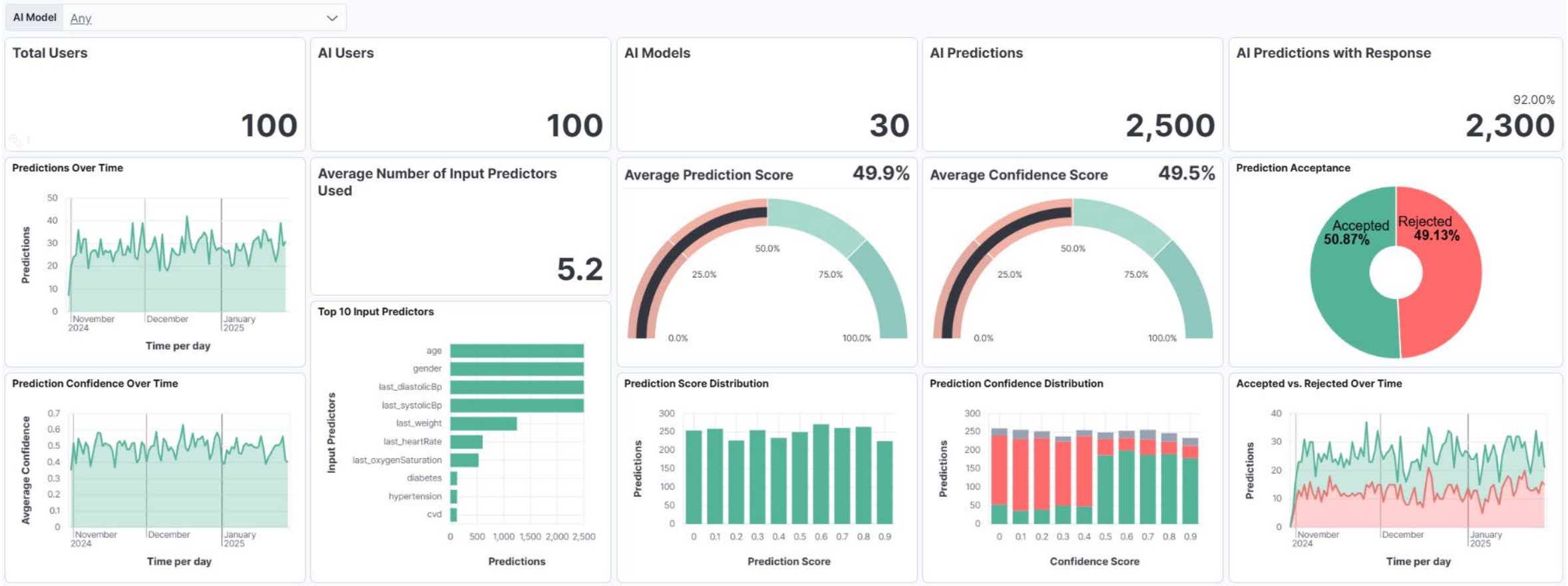
Aligns with established standards and ethical design principles

Integrates W3C PROV, PROV-ML, Model Cards, and FUTURE-AI guidelines.

Serves as a baseline reference for continuous oversight

Captures deployment-time details to support tracking of changes and guiding future updates.

Continuous monitoring



AI4HF

Data foundations and regulatory clarity

Access to high-quality data is key: Interoperability is slowed by data fragmentation

Need for improved legal clarity

- **Evidence** requirements,
- Coherent and clear legal framework for **liability** and accountability,
- **Post-marketing** monitoring.

Need for AI-tailored regulation

- Ongoing **performance monitoring** within routine healthcare,
- **Detection of drift**, bias and unintended effects,
- **Integration** into **post-market** surveillance systems.

Towards a coordinated European approach

Role of clinicians and academics

- **Defining** clinically **meaningful** endpoints and phenotypes,
- **Supporting** independent validation,
- **Ensuring integration** into clinical workflows.

Contributions from

- **Supporting** common **frameworks** for evaluation and use,
- **Incorporating AI** into clinical **guidelines** and standards,
- **Facilitating** training and capacity building.

coordinated, multi-stakeholder approach

- **Common data standards** and **infrastructures**,
- Shared **evaluation frameworks**,
- Practical **deployment** guidance for healthcare systems.